REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB1310aH

Product name(s): Glosset Ace

Chemical active substances:

Aclonifen, 540 g/L
Flufenacet, 60 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: December 2021

MS Finalisation date: 25/08/2022

After commenting: 14/12/2022

Version history

When	What
December 2021	First submission by the applicant for the authorization of a new formulation
August 2022	First zRMS PL evaluation
December 2022	Corrections made by zRMS PL after commenting round

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product named Glosset Ace (product code: GLOB1310aH) containing 540 g/L Aclonifen and 60 g/L of Flufenacet formulated as a suspension concentrate (SC) for pre-emergence and early post-emergence treatment on winter cereals. This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013. GLOB1310aH was not the representative formulation during the EU Review of the active substances.

Poland is the zRMS of GLOB1310aH for the Central zone and Belgium, Germany, Hungary, Ireland, Romania, Slovenia and Slovakia are cMS.

The Annex II data on Aclonifen and Flufenacet are out of data protection at the EU level. The sources of both active ingredients are already approved in the EU, the evaluation report can be found on CIRCA (see part C for more information on the sources).

Regarding the product data, all necessary data are owned by the company Globachem NV itself.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland, Glosset Ace	Belgium, Glosset Ace Germany, Glosset Ace Hungary, Glosset Ace Ireland, Glosset Ace Romania, Glosset Ace Slovenia, Glosset Ace Slovakia, Glosset Ace

0.1.3 Regulatory history of the active(s)

0.1.3.1 Aclonifen

Table 0.1-2: Summary of regulatory history of CAS No: 74070-46-5

Status	
Approved in EU	Y
Original Inclusion Directive	Commission Implementing Regulation (EU):

Status	
or Commission Implementing Regulation	COMMISSION DIRECTIVE 2008/116/EC Reg. No 540/2011
RMS	Federal Republic of Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2010
Date of final Commission (re-registration) deadline (Step 2)	31.01.2014
Current expiration of approval	31.07.~~2022~~ 2023
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- The specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material;
- The protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure;
- The residues in rotational crops and evaluate the dietary exposure of consumers;
- The protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate.

The SANCO report for Aclonifen (SANCO/161/08 – rev. 1 – 27/11/2009) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 21/10/2008.

Table 0.1-3: Information on minimum purity of Aclonifen

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report ****
97 % (SANCO/161/08 – rev. 1)	98 % Equivalence report available: Y RMS: DE

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

0.1.3.2 Flufenacet

Table 0.1-4: Summary of regulatory history of CAS No: 142459-58-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	COMMISSION DIRECTIVE 2003/84/EC, COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 and REGULATION (EU) No 2021/1449
RMS	Poland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2004
Date of final Commission (re-registration) deadline (Step 2)	30.06.2005
Current expiration of approval	31.10.2022
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,
- the protection of algae and aquatic plants,
- the protection of operators.

The SANCO report for flufenacet (SANCO/9469/VI/98 – final) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 03.07.2003.

Table 0.1-5: Information on minimum purity of flufenacet

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
950 g/kg	95% Equivalence report available: Y RMS: IE, UK

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

The formulated product Glosset Ace containing 540 g/l aclonifen and 60 g/l flufenacet is classified for human health reason as Skin Sens. 1 and Carc. 2 (Regulation EC No 1272/2008). According to the model calculations, it can be concluded that the risk for the operator, worker and bystander is acceptable. The proposed use of aclonifen and flufenacet do not represent unacceptable chronic risks for the consumers. No unacceptable risk to birds, mammals, non-target aquatic organisms, bees, non-target arthropods, non-target plants is expected following the application of Glosset Ace according to proposed use. The efficacy of Glosset Ace was sufficiently demonstrated for use in winter wheat, barley, triticale and rye.

Uses to be considered safe on the basis of EU methodology:

See: Appendix 1

Uses to be considered non-safe on the basis of EU methodology:

See: Appendix 1

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See: Appendix 1

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1.0, date: 2021-12-03

PPP (product name/code):	Glosset Ace/GLOB1310aH	Formulation type:	SC [a, b]
Active substance 1:	Aclonifen	Conc. of as 1:	540 g/L [c]
Active substance 2:	Flufenacet	Conc. of as 2:	60 g/L [c]
Safener:	/	Conc. of safener:	NA [c]
Synergist:	/	Conc. of synergist:	NA [c]
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Rye (SECCW) Winter Triticale (TTLWI)	F	**Well controlled (S):** *Apera spica-venti, Poa annua, Tripleuspermum inodorum, Papaver rhoeas, Stellaria media, Veronica persica,*) **Partially controlled (MS):** *Veronica hederifolia*	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 1.5 L/ha b) 1.5 L/ha	a) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha b) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha	150-300	Not relevant, see application stage	/	

2	PL	Winter Oat (AVESW) Winter Durum Wheat (TRZDW)	F	Annual weeds (BBBBB)	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 1.5 L/ha b) 1.5 L/ha	a) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha b) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha	150-300	Not relevant, see application stage	/	
3	PL	Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Rye (SECCW) Winter Triticale (TTLWI)	F	**Well controlled (S):** *Apera spica-venti, Poa annua, Tripleuspermum inodorum, Papaver rhoeas, Stellaria media, Veronica persica, Veronica hederifolia* **Partially controlled (MS):** *Alopecurus myosuroides, Galium aparine*	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 2 L/ha b) 2 L/ha	a) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha b) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha	200-300	Not relevant, see application stage	/	
4	PL	Winter Oat (AVESW) Winter Durum Wheat (TRZDW)	F	Blackgrass (ALOMY)	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 2 L/ha b) 2 L/ha	a) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha b) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha	200-300	Not relevant, see application stage	/	
5	BE DE HU IE RO SI SK	Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Oat (AVESW) Winter Rye (SECCW) Winter Triticale (TTLWI) Winter Durum Wheat (TRZDW)	F	**Well controlled (S):** *Apera spica-venti, Poa annua, Myosotis arvensis, Papaver rhoeas, Stellaria media, Veronica persica, Veronica hederifolia, Matricaria chamomilla, Thlaspi arvense* **Partially controlled (MS):** *Alopecurus myosuroides, Tripleuspermum inodorum*	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 1.5 L/ha b) 1.5 L/ha	a) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha b) 0.810 kg Aclonifen/ha + 0.090 kg Flufenacet/ha	150-300	Not relevant, see application stage	/	
6	BE DE HU IE RO SI	Winter Wheat (TRZAW) Winter Barley (HORVW) Winter Oat (AVESW)	F	**Well controlled (S):** *Apera spica-venti, Poa annua, Myosotis arvensis, Tripleuspermum inodorum, Papaver rhoeas, Stellaria media, Veronica*	Normal downward spraying	BBCH 00-09 (Sep-Dec)	a) 1 b) 1	/	a) 2 L/ha b) 2 L/ha	a) 1.08 kg Aclonifen/ha + 0.120 kg Flufenacet/ha b) 1.08 kg Aclonifen/ha	200-300	Not relevant, see application stage	/	

	SK	Winter Rye (SECCW) Winter Triticale (TTLWI) Winter Durum Wheat (TRZDW)		*persica, Veronica hederifolia, Matricaria chamomilla, Thlaspi arvense* **Partially controlled (MS):** *Alopecurus myosuroides*						+ 0.120 kg Flufenacet/ha				

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3